K020842

MAY 15 2002

Date: March 13, 2002

510(k) SUMMARY

SUBMITTED BY: Becton Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
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CONTACT NAME: Michelle B. Bandy, Regulatory Affairs Specialist

DATE PREPARED: March 13, 2002

DEVICE TRADE NAME: Ertapenem 10 µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs

DEVICE COMMON NAME: Antimicrobial Susceptibility Test Discs

DEVICE CLASSIFICATION: 21 CFR§866.1620, Class II (Product Code JTN), Susceptibility Test Discs, Antimicrobial

PREDICATE DEVICE: Other BBL™ Sensi-Disc™
(eg, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™)

INTENDED USE:

Antimicrobial Susceptibility Test Discs are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Ertapenem 10 µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Ertapenem of a wide range of bacteria, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer, Merck & Co., Inc. and received FDA approval under NDA Number 21-337.

510(k) SUMMARY

INDICATIONS FOR USE:

Use of Ertapenem 10 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Ertapenem. Ertapenem has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the Merck & Co., Inc. package insert for this antimicrobic.

Active *In Vitro* and in clinical infections against:

Aerobic gram-positive microorganisms
Staphylococcus aureus (methicillin-susceptible strains only)
Streptococcus agalactiae
Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes

Aerobic gram-negative microorganisms
Escherichia coli
Haemophilus influenzae (beta-lactamase negative strains only)
Klebsiella pneumoniae

Active *In Vitro* Against:

Aerobic gram-positive microorganisms
Streptococcus pneumoniae (penicillin-intermediate strains only)

Aerobic gram-negative microorganisms
Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Haemophilus influenzae (beta-lactamase positive strains)
Haemophilus parainfluenzae
Klebsiella oxytoca (excluding ESBL producing strains)
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Serratia marcescens

DEVICE DESCRIPTION:

Ertapenem 10 µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Ertapenem supplied by the manufacturer, Merck & Co., Inc. Each Ertapenem disc is clearly marked on both sides with the agent and drug content. Ertapenem cartridges each contain 50 impregnated discs that are packed as either a single cartridge in a single box, or in a package containing ten cartridges. Ertapenem discs are used for semi-quantitative *in vitro* susceptibility evaluations by the agar diffusion test method.

Agar diffusion susceptibility methods employing dried filter paper discs impregnated with specific concentrations of antimicrobial agents were developed in the 1940s. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the National Committee for Clinical Laboratory Standards (NCCLS) and is periodically updated.

DEVICE PRINCIPLE:

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus* species] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the discs are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The categorical interpretation [susceptible (S), intermediate (I), or resistant (R)] for the organism being tested with the antimicrobial agent is made by comparing zone diameters to those found in the respective organism tables of NCCLS Document M2-A7 ("Performance Standards for Antimicrobial Disk Susceptibility Tests - Seventh Edition, Approved Standard", 1/00) and of NCCLS Document M100-S12 ("Performance Standards for Antimicrobial Susceptibility Testing", Twelfth Informational Supplement, 1/02).

DEVICE COMPARISON:

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ertapenem 10 µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ciprofloxacin 5 µg in that:

- Both methods are for antimicrobial susceptibility testing using paper discs impregnated with an antimicrobial agent.
- Both methods have the same intended use.
- Both methods provide the user with antimicrobic minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations (S/I/R) using the measured zone diameters against NCCLS Approved Standards M2 and M100.
- Both methods use pure cultures of bacterial isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ertapenem 10 µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ertapenem 10 µg is a susceptibility test that uses discs impregnated with the antimicrobic Ertapenem at a concentration of 10 µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs - Ciprofloxacin 5 µg is a susceptibility test that uses discs impregnated with the antimicrobic Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disc - Ertapenem 10 µg is a susceptibility test used to test a different battery of microorganisms than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disc - Ciprofloxacin 5 µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the INVANZ™ (Ertapenem for injection) Merck & Co., Inc. drug package insert, "Susceptibility Tests: Diffusion Techniques".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 5 2002

Ms. Michelle B. Bandy
Regulatory Affairs Specialist
BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152

Re: k020842
Trade/Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs, Ertapenem 10µg
Regulation Number: 21 CFR 866.1620
Regulation Name: Susceptibility Test Discs
Regulatory Class: Class II
Product Code: JTN
Dated: March 13, 2002
Received: March 15, 2002

Dear Ms. Bandy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Discs, Ertapenem 10µg

Indications for Use:

Use of Ertapenem 10 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Ertapenem. Ertapenem has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the Merck & Co., Inc. package insert for this antimicrobic.

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Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes

Aerobic gram-negative microorganisms
Escherichia coli
Haemophilus influenzae (beta-lactamase negative strains only)
Klebsiella pneumoniae

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020840

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)